

US010500061B2

(12) United States Patent

Moore et al.

(54) ADJUSTABLE SPINAL IMPLANT

(71) Applicant: **K2M, Inc.**, Leesburg, VA (US)

(72) Inventors: Jennifer Moore, Leesburg, VA (US);

Stephen Truesdell, Reston, VA (US)

(73) Assignee: **K2M, Inc.**, Leesburg, VA (US)

(*) Notice: Subject to any disclaimer, the term of this

patent is extended or adjusted under 35

U.S.C. 154(b) by 5 days.

(21) Appl. No.: 15/752,369

(22) PCT Filed: Aug. 15, 2016

(86) PCT No.: PCT/US2016/046991

§ 371 (c)(1),

(2) Date: Feb. 13, 2018

(87) PCT Pub. No.: **WO2017/027873**

PCT Pub. Date: Feb. 16, 2017

(65) Prior Publication Data

US 2019/0000644 A1 Jan. 3, 2019

Related U.S. Application Data

- (60) Provisional application No. 62/204,542, filed on Aug. 13, 2015.
- (51) Int. Cl.

 A61F 2/44 (2006.01)

 A61F 2/46 (2006.01)

 A61F 2/30 (2006.01)

(10) Patent No.: US 10,500,061 B2

(45) **Date of Patent:** Dec. 10, 2019

(58) Field of Classification Search

CPC A61F 2/4455–447; A61F 2/4425; A61F

2002/30537–30538

See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

OTHER PUBLICATIONS

International Search Report dated Oct. 28, 2016 in PCT/US2016/046991.

(Continued)

Primary Examiner — Eduardo C Robert

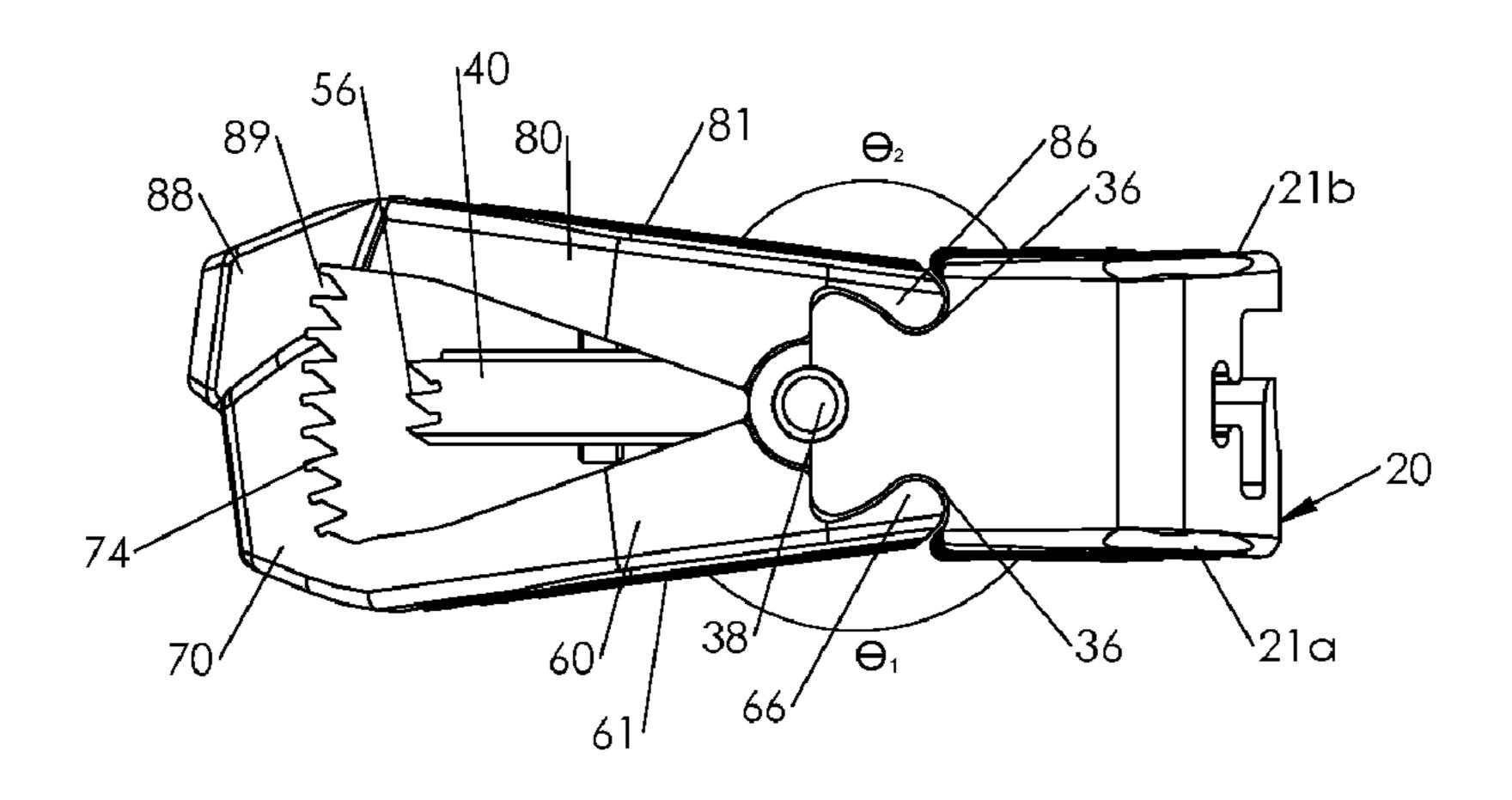
Assistant Examiner — Michelle C Eckman

(74) Attorney, Agent, or Firm — Lerner, David,
Littenberg, Krumholz & Mentlik, LLP

(57) ABSTRACT

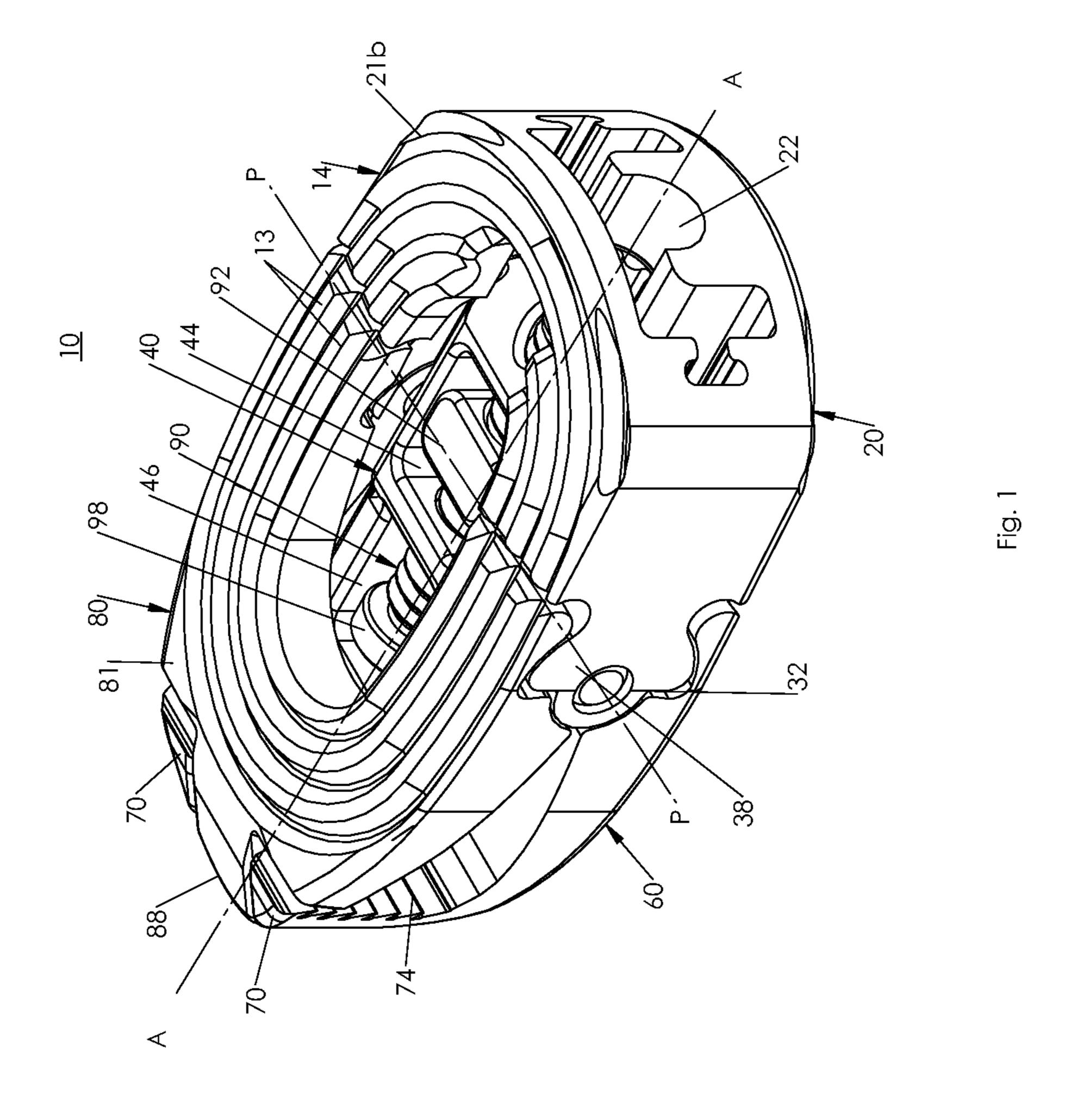
An adjustable spinal implant includes a fixed segment that slidably supports a locking segment and pivotally supports an upper segment and a lower segment relative to one another. The locking segment translates within a channel defined by the fixed segment between locked and unlocked positions. In the locked position, the upper and lower segments are fixed relative to one another and to the fixed segment. In the unlocked position, the upper and lower segments are pivotal relative to one another and to the fixed segment. The adjustable spinal implant includes a locking mechanism including a locking screw to translate the locking segment between locked and unlocked positions.

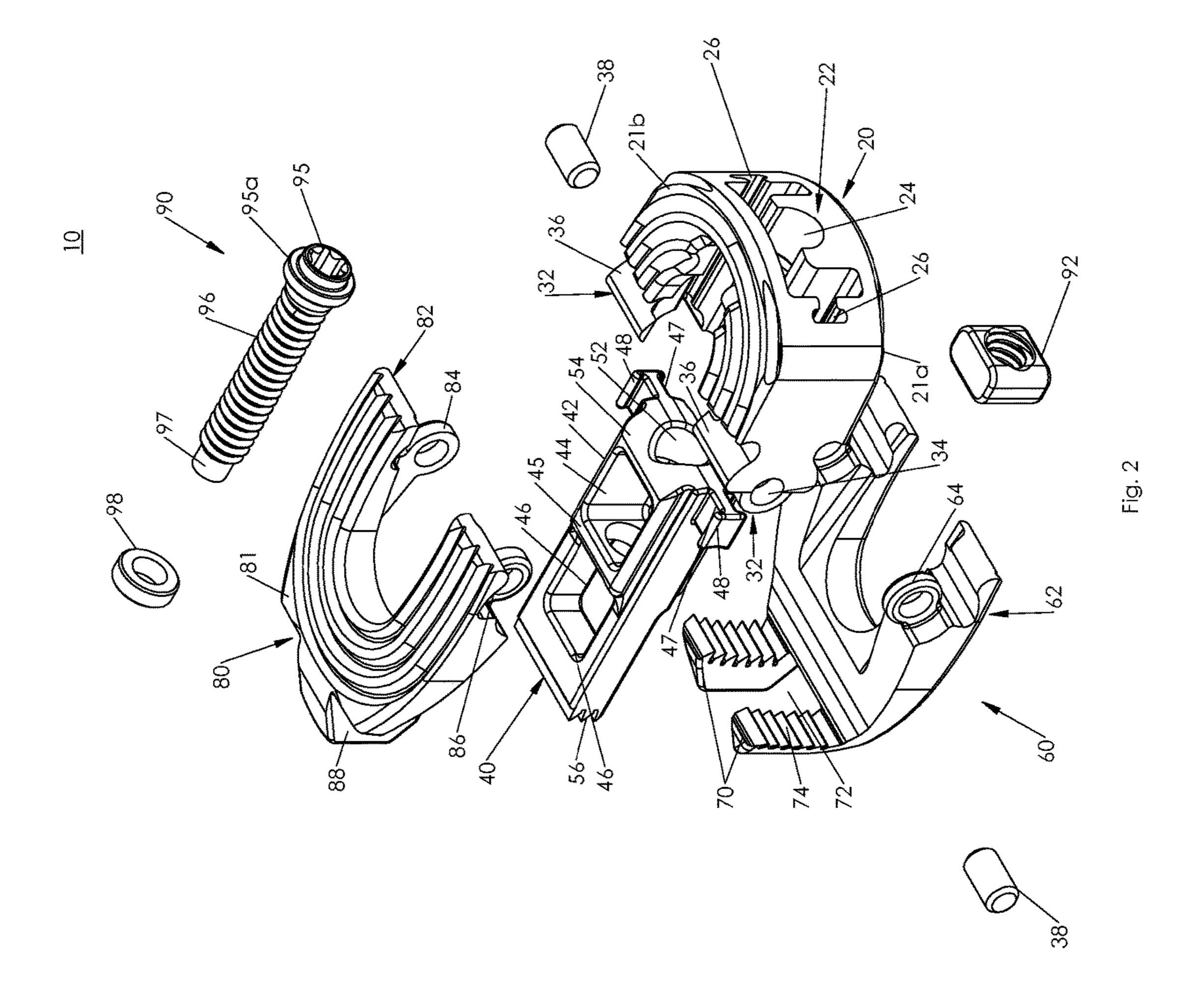
20 Claims, 5 Drawing Sheets

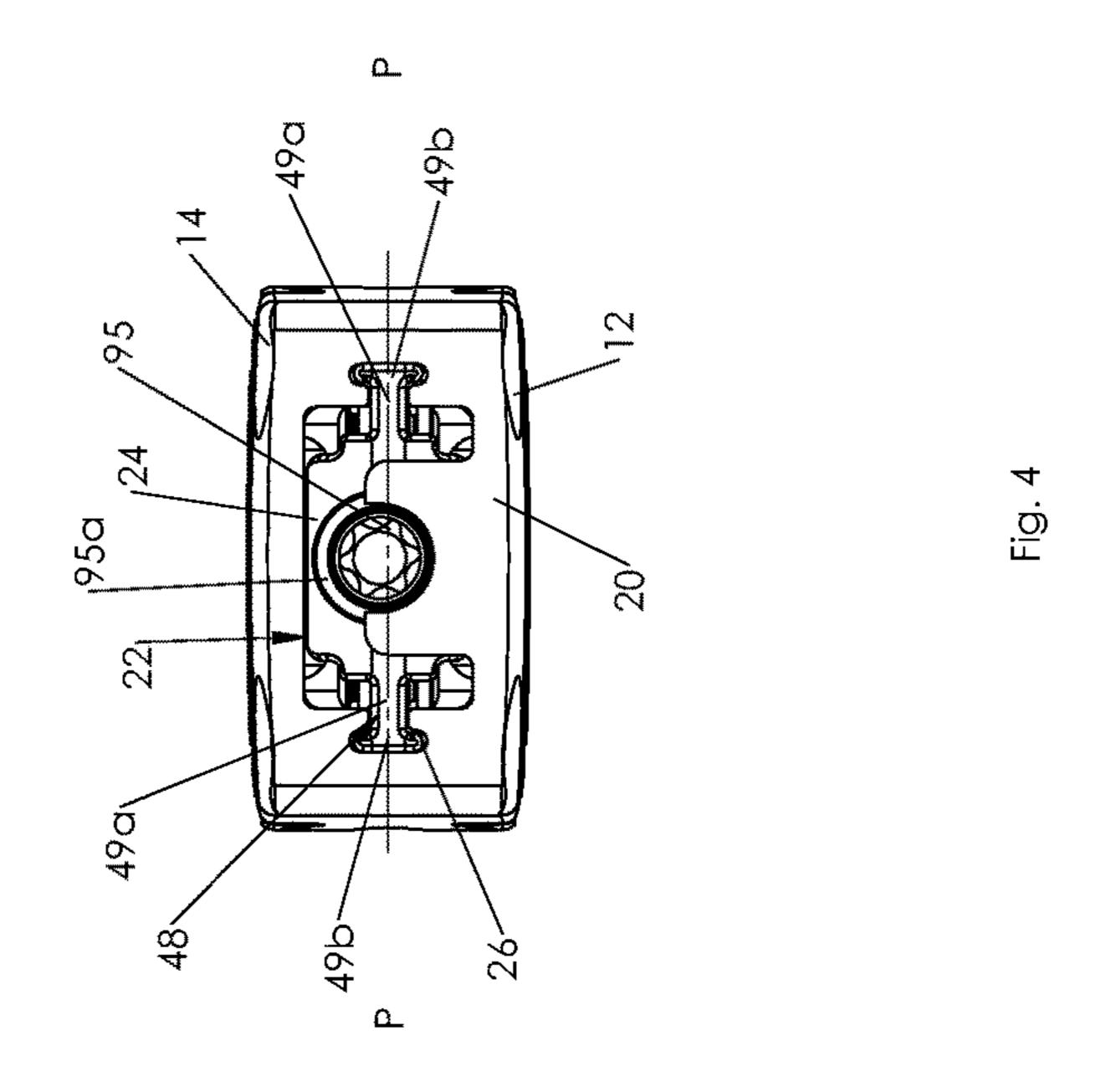


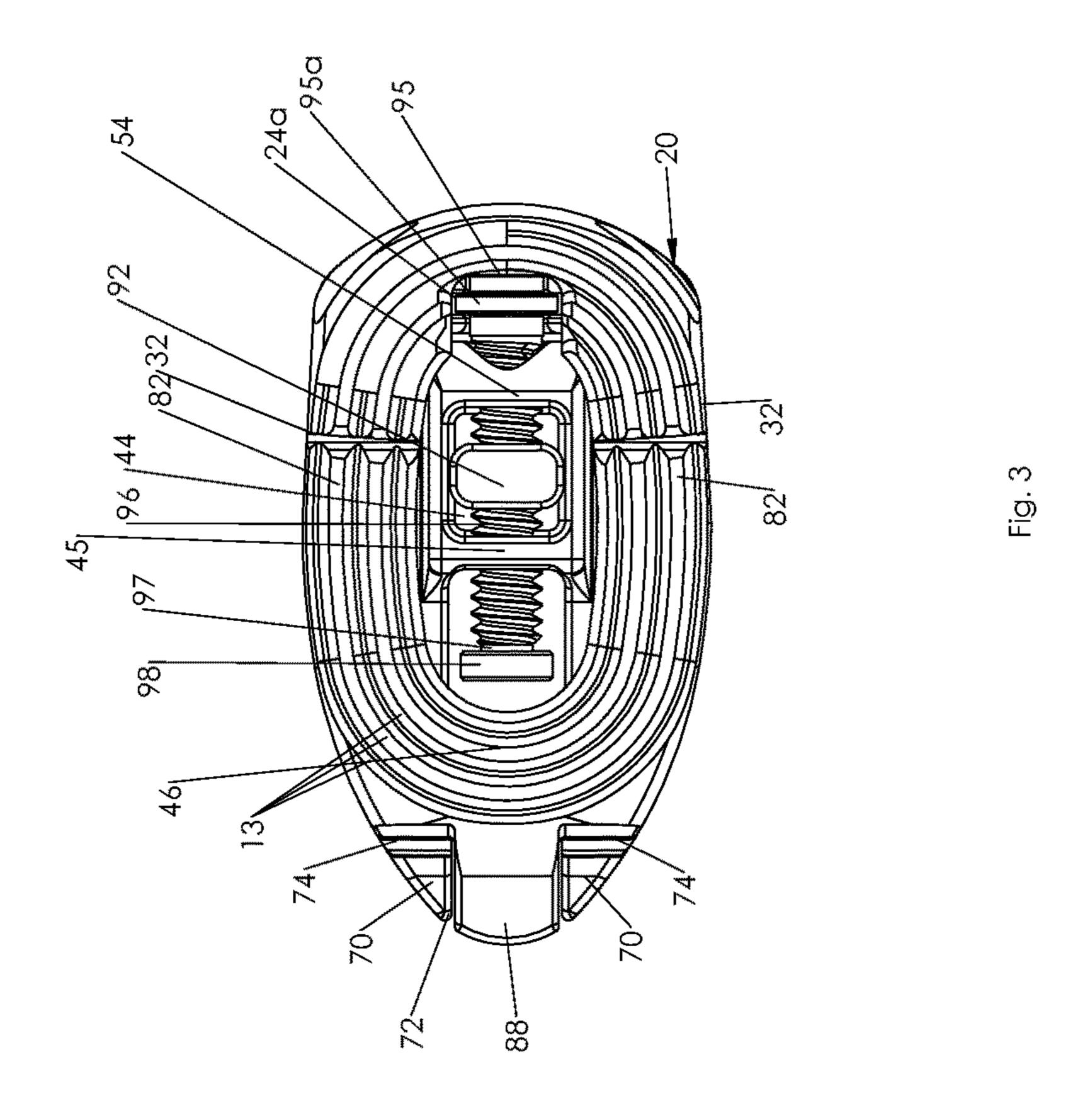
US 10,500,061 B2 Page 2

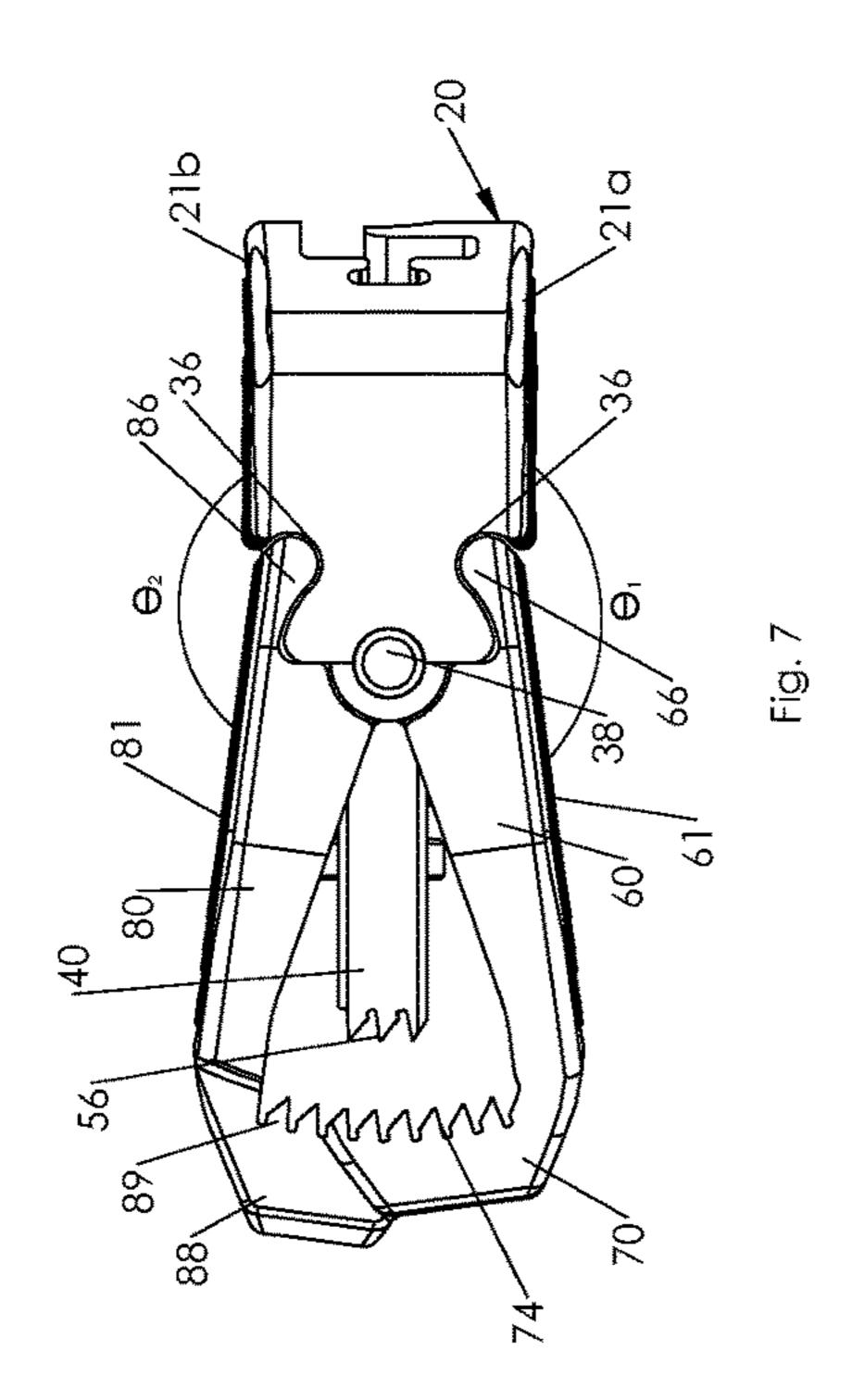
(52)	U.S. Cl.					2016/0022438	A1*	1/2016	Lamborne	A61F 2/4455
(32)		• • • • • • • •		F 2002/3052 (2013	, ·	2016/0030190	A1*	2/2016	Robinson	623/17.16 A61F 2/447
	(2			5 (2013.01); <i>A61F 2</i> 7 <i>2002/30507</i> (2013		2016/0038305	A1*	2/2016	Weiman	623/17.16 A61F 2/4455
	•	20	02/30538	3 (2013.01); A61F 2	002/30556	2016/0089247			Nichols	623/17.16
(2013.01); A61F 2002/30579 (2013.01); A61F 2002/30772 (2013.01); A61F 2002/30822						2016/0095716			Baynham	623/17.16
		((2013.01)); A61F 2002/30904	(2013.01)					623/17.16
(56) Referen				ces Cited	2016/0100951			Suddaby	623/17.16	
	-	U.S. 1	PATENT	DOCUMENTS					Stinchfield	623/17.15
	/			Lentner A		2016/0120660	A1*	5/2016	Melkent	A61F 2/4455 623/17.16
				Ferree A	623/17.11	2016/0166396	A1*	6/2016	McClintock	A61F 2/30771 623/17.16
2003	/0236520	A1*	12/2003	Lim A	A61B 17/025 606/99				Deridder Loebl	
2004	/0044411	A1*	3/2004	Suddaby	. A61F 2/28 623/17.15					623/17.16
2005	/0113916	A1*	5/2005	Branch, Jr					Overes Loebl	
	, 0 110 5 10		o, 2 000		623/17.11				Faulhaber	
2006	/0030943	A1*	2/2006	Peterman A	A61F 2/4455				Packer	
					623/17.11				Baynham	
2009	/0265007	A 1	10/2009	Colleran					Foley	
2010	/0191336	A1*	7/2010	Greenhalgh A	A61F 2/4455				Weiman	
					623/17.16		_		Hleihil	
				Melkent et al.		2017/0105844			Kuyler	
2012	/0303124	Al*	11/2012	McLuen A		2017/0112630			Kuyler	
2012	/0121000	A 1 *	5/2012	C1- A 4	623/17.16	2017/0112631 2017/0112632			Kuyler Dmushewsky	
2013	/0131808	Al	3/2013	Suh Ac	623/17.16	2017/0112032			Baynham	
2013	/0158664	Δ1*	6/2013	Palmatier		2017/0119543			Dietzel	
2015	0130004	711	0/2013	1 amatro	623/17.16	2017/0156885	A1*		Zur	
2013	/0197642	A1*	8/2013	Ernst					Field	
					623/17.16				Bjork	
2013	/0274883	A1*	10/2013	McLuen	A61F 2/447				Miller Dewey	
2014	(000 4000		4/2014		623/17.16	2017/0210043			Overes	
2014	/0094922	Al*	4/2014	Abdou						623/17.16
2014	/0114420	Δ1*	4/2014	Robinson	623/17.16 A61F 2/447				Carnes	
2011	70111120	711	1/2011	1001113011	623/17.16				Richerme	
2014	/0148904	A1*	5/2014	Robinson					Black	
					623/17.16				Dewey	
2014	/0194991	A1*	7/2014	Jimenez					Sharifi-Mehr	
2014	/0257486	A 1 *	0/2014	Alheidt	623/17.15				Arnin	
2014	/023/460	AI	9/2014	Ameiat	623/17.15				Eisen	
2014	/0277508	A1*	9/2014	Baynham					EisenBaynham	
	, , , , , , , , , , , , , , , , , , , ,			2007 111101111					Levieux	
2014	/0296983	A1*	10/2014	Fauth	A61F 2/447	2018/0071111			Sharifi-Mehr	
• • • •	1001555			TT7 '	623/17.16	2018/0116811			Bernard	
2014	/0316522			Weiman		2018/0116812			Bernard Kuyler	
2014	/0343677			Davis	623/17.16 461F 2/447				Bernard	
2014	70343077	711			623/17.15				Sharabani	
2014	/0343678	A1*		Suddaby					Robinson	
					623/17.16				Brotman	
2015	/0018954	A1*		Loebl A					Luu	
2015	/0057755	A 1 *		Suddaby					Werner	
2013	, 5551133		2,2013	Saddley	623/17.16				Moore	
2015	/0148908	A1*	5/2015	Marino A					Ludwig	
				_	623/17.16				Suddaby Suddaby	
2015	/0257894	A1*	9/2015	Levy	A61F 2/442 623/17.15		_		<i>y</i>	· · · ·
2015	/0272743	A1*	10/2015	Jimenez	A61F 2/447		OT]	HER PU	BLICATIONS	
2015	/0351025	Δ1*	12/2015	Emerick	623/17.16 A61F 2/447	International Pro	elimin	arv Renor	t on Patentability	dated Feb. 13.
2013	0001740	$\Delta \Gamma$	12/2013	LINCINCK	623/17.16	2018, issued in		•		
2015	/0374508	A1*	12/2015	Sandul		,	· •			
_ 2					623/17.16	* cited by exa	miner	•		
						•				

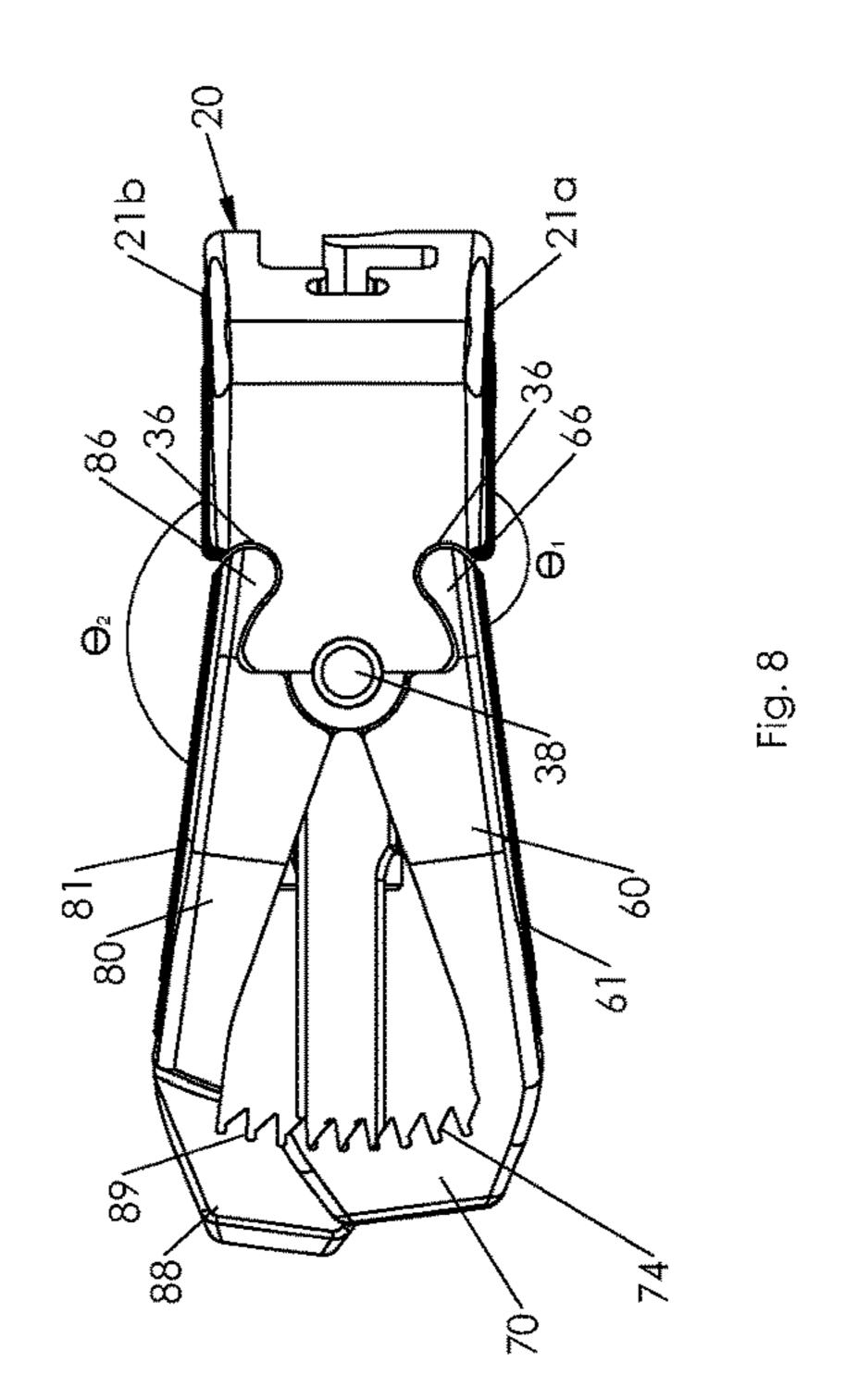


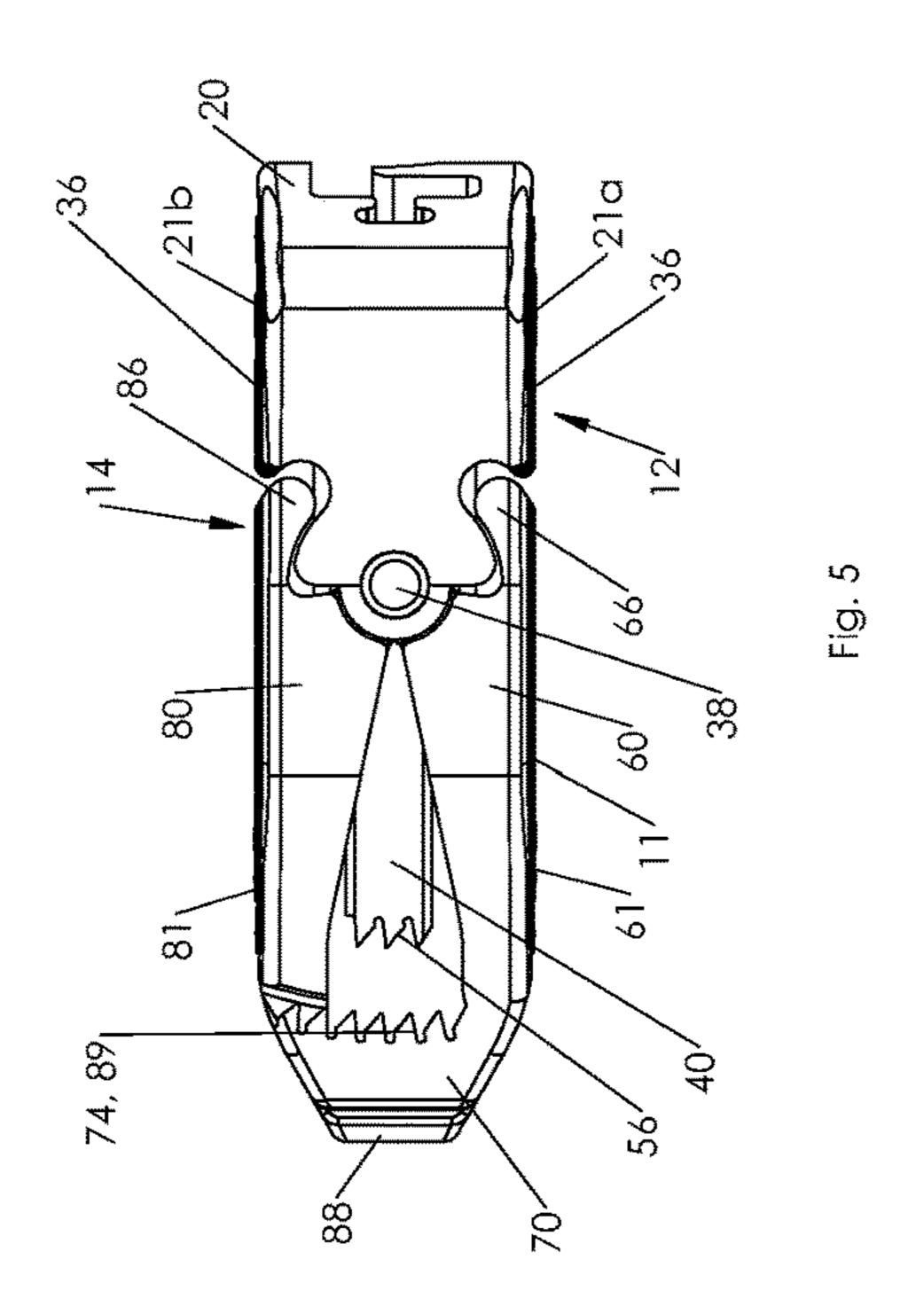


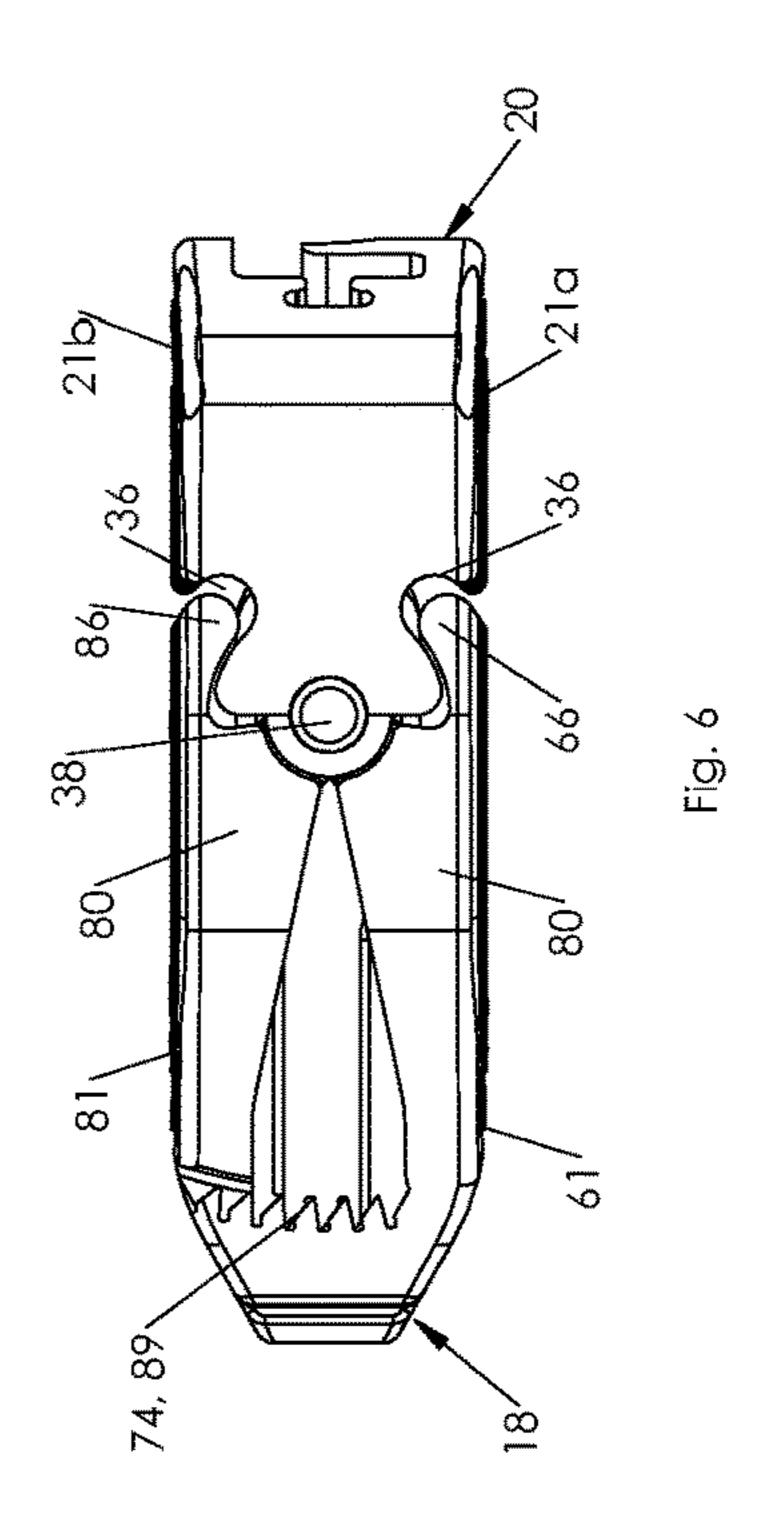


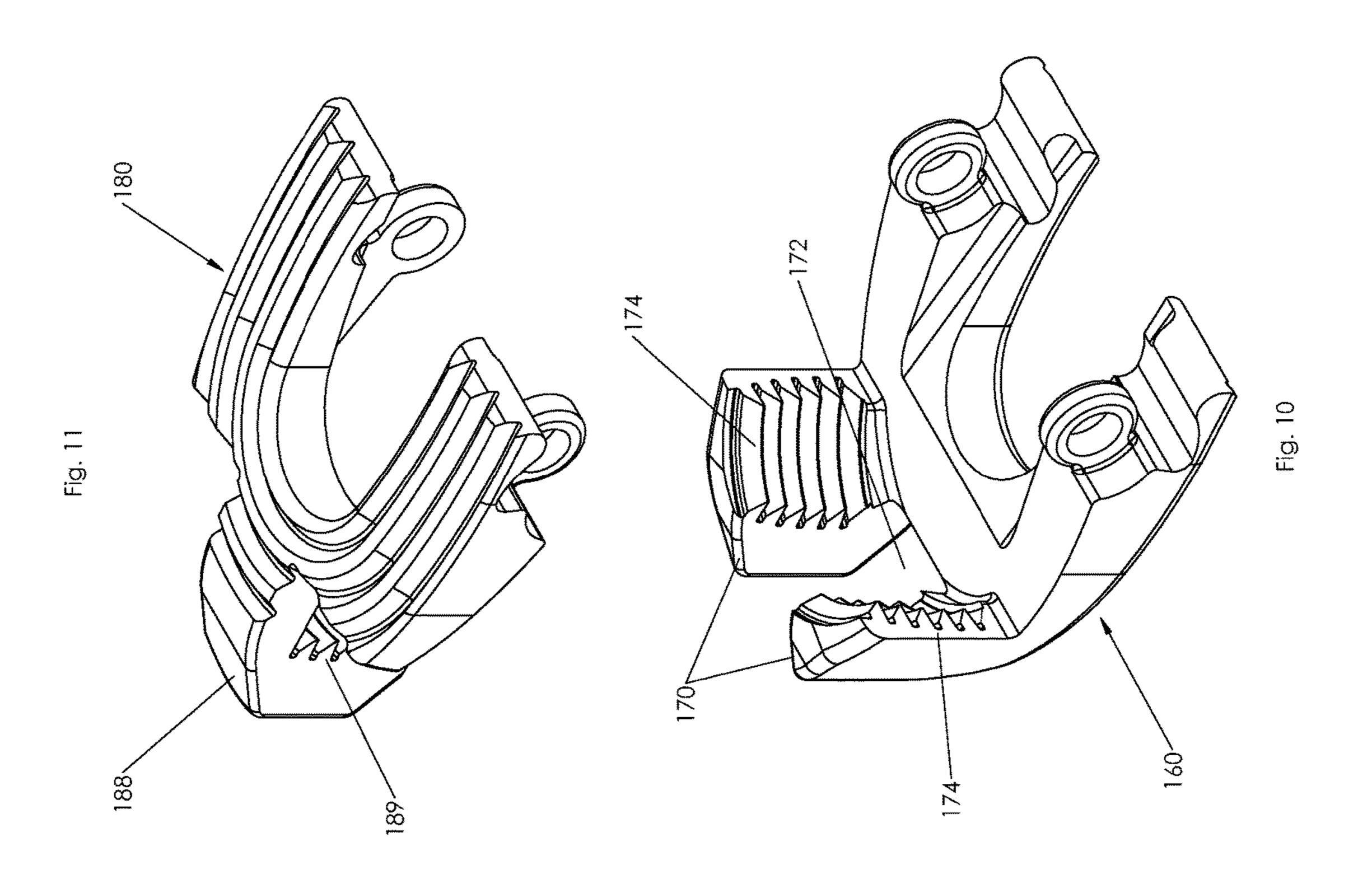


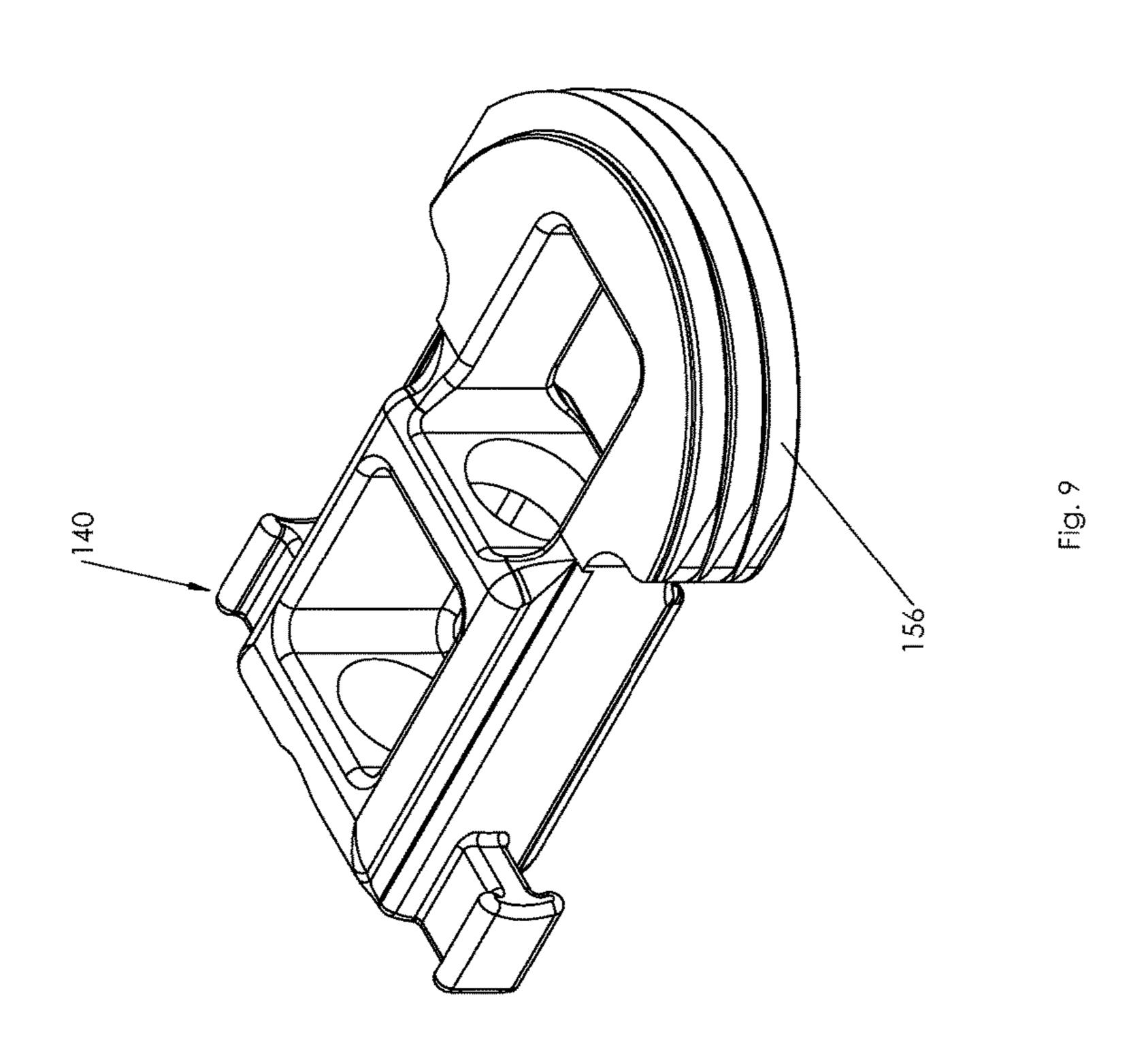












ADJUSTABLE SPINAL IMPLANT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a National Stage Entry of PCT/US2016/046991, filed Aug. 15, 2016, which claims the benefit of, and priority to, U.S. Provisional Patent Application Ser. No. 62/204,542, filed Aug. 13, 2015. The entire contents of each of the above applications are hereby ¹⁰ incorporated by reference.

BACKGROUND

1. Technical Field

The present disclosure relates to a device for use in orthopedic surgeries and, more specifically, to an adjustable spinal implant and a method for inserting an adjustable spinal implant into an intervertebral space.

2. Discussion of Related Art

Stresses acting upon the human spine (or "vertebral column") may result in a variety of problems or disease 25 states. For example, intervertebral discs have a high propensity to degenerate. Overt or covert trauma occurring in the course of repetitive activities disproportionately affects the more highly mobile areas of the spine. Disruption of a disc's internal architecture leads to bulging, herniation, or 30 protrusion of pieces of the disc and eventual disc space collapse. Any resulting irritation (e.g., mechanical or chemical) of surrounding neural elements (e.g., spinal cord and nerves) may cause pain that is attended by varying degrees of disability. In addition, loss of disc space height relaxes 35 tension on the longitudinal spinal ligaments, thereby contributing to varying degrees of spinal instability such as spinal curvature.

The time-honored method of addressing the issues of neural irritation and instability resulting from severe disc 40 damage have largely focused on removal of the damaged disc and fusing the adjacent vertebral elements together. Removal of the disc relieves the mechanical and chemical irritation of neural elements, while osseous union (i.e., bone knitting) solves the problem of instability.

While cancellous bone appears ideal to provide the biologic components necessary for osseous union to occur, it does not initially have the strength to resist the tremendous forces that may occur in the intervertebral disc space, nor does it have the capacity to adequately stabilize the spine 50 until long term bony union occurs. For these reasons, interbody fusion using bone alone may have an unacceptable rate of bone graft migration, expulsion, or nonunion due to structural failures of the bone or residual degrees of motion that retard or prohibit bony union. Intervertebral prostheses 55 in various forms have therefore been used to provide immediate stability and to protect and preserve an environment that fosters growth of grafted bone such that a structurally significant bony fusion can occur.

Limitations of present-day intervertebral implants can be significant and revolve largely around the marked variation in disc space shape and height which results from either biologic variability or pathologic change. For example, if a disc space is 20 mm in height, a circular implant bridging this gap requires a minimum height of 20 mm just to contact 65 the end plate of the vertebral bone. Generally, end plate disruption must occur to allow a generous bony union,

2

meaning that an additional 2-3 mm must be added on either end, resulting in a final gap or space of 24-26 mm to accommodate the implant. During implantation from an anterior approach (i.e., from the front of the body), excessive retraction (i.e., pulling) is often required on the great blood vessels. On the other hand, during a posterior approach, large implant diameters may require excessive traction on neural elements for adequate placement, even if all posterior bony elements are removed. In some instances, an adequate implant size cannot be inserted posteriorly, particularly if there is a significant degree of ligamentous laxity requiring higher degrees of distraction to obtain stability by tightening the annular ligamentous tension band. Compromising on implant size risks sub-optimal stability or a loose implant, which has a greater chance for migration within or expulsion from the disc space. The alternative of excessively retracting neural elements to facilitate a posterior implant application may result in damage to the neural elements.

Therefore, a need exists for an adjustable implant that can 20 be inserted in a collapsed position in order to prevent over retraction of the anatomy or substandard implant sizing and once the implant is in place be expanded to fill the anatomical space appropriately including a desired amount of lordosis.

SUMMARY

Adjustable spinal implants may serve to stabilize adjacent vertebral elements, thereby facilitating the development of a bony union between them and thus long term spinal stability while being inserted in a collapsed position.

In an aspect of the present disclosure, an adjustable spinal implant includes a fixed segment, a locking segment, a lower segment, an upper segment, and a locking mechanism. The fixed segment defines a channel that is disposed about a longitudinal axis of the spinal implant. The locking segment is translatable within the channel of the fixed segment along the longitudinal axis between locked and unlocked positions. The locking segment defines a proximal opening that passes vertically through a body of the locking segment and has locking teeth at a distal end portion thereof. The lower segment is pivotally coupled to the fixed segment about a pivot axis that is transverse to the longitudinal axis. The lower segment has a distal end portion that includes teeth that oppose the locking teeth. The upper segment is pivotally coupled to the fixed segment about the pivot axis. The upper segment has a distal end portion which includes teeth that oppose the locking teeth. The adjustable spinal implant has a collapsed configuration wherein the distal end portions of the lower and upper segments define a first height and an expanded configuration wherein the distal end portions of the lower and upper segments define a second height greater than the first height. The locking mechanism is engageable with the locking segment to translate the locking segment longitudinally between the locked and unlocked positions to fix the lower and upper segments relative to the fixed segment.

In aspects, the locking teeth of the locking segment are engaged with the teeth of the lower and upper segments to fix the lower and upper segments relative to the fixed segment to define the locked position.

In some aspects, a bottom surface of the spinal implant is defined by a lower surface of the lower segment and a lower surface of the fixed segment. In the collapsed configuration the lower surfaces of the lower segment and the fixed segment are disposed with the same linear plane and in the expanded configuration the lower surface of the lower

segment and the lower surface of the fixed segment define a non-zero first angle therebetween. The first angle may be in a range of about 135° to about 179°. The top surface of the spinal implant may be defined by an upper surface of the upper segment and an upper surface of the fixed segment. In the collapsed configuration, the upper surfaces of the upper segment and the fixed surface are disposed within the same linear plane. In the expanded configuration, the upper surface of the upper segment and the upper surface of the fixed segment may define a non-zero section angle therebetween. The second angle may be in a range of about 135° to about 179°.

In certain aspects, the distal end portion of the lower segment may include tines that define a gap therebetween. Each of the tines may include the teeth that oppose the 15 locking teeth. The distal end portion of the upper segment may include a tongue that is positionable within the gap defined between the tines of the lower segment. The tongue may include the teeth that oppose the locking teeth.

In particular aspects, the locking mechanism may include 20 FIG. 1; a locking screw that is disposed within the channel of the fixed segment and the passage of the locking segment. The locking mechanism may include a threaded insert that is disposed on the threaded shank of the locking screw that engages walls defining the proximal opening of the locking 25 FIG. 1 is segment to transition the locking segment between the locked and unlocked positions.

In certain aspects, the locking teeth are arcuate in a plane parallel to the longitudinal axis. The locking teeth may have a semi-circular profile in the plane parallel to the longitu- 30 dinal axis.

In another aspect of the present disclosure, a method of inserting an adjustable spinal implant includes positioning an adjustable spinal implant into an intervertebral space in a collapsed configuration, unlocking the adjustable spinal 35 implant when the adjustable spinal implant is positioned within the intervertebral space, transitioning the adjustable spinal implant to an expanded configuration, and locking the adjustable spinal implant in the expanded configuration. The distal end portion of the adjustable spinal implant has a first 40 height in the collapsed configuration. Unlocking the adjustable spinal implant includes disengaging locking teeth of a locking segment from teeth of a lower segment and teeth of an upper segment. Transitioning the adjustable spinal implant to the expanded configuration includes pivoting the 45 lower segment, the upper segment, or both segments of the adjustable spinal implant about a pivot axis is defined by a fixed segment of the adjustable spinal implant such that a distal end portion of the adjustable spinal implant has a second height greater than the first height. Locking the 50 adjustable spinal implant in the expanded configuration includes engaging the locking teeth of the locking segment with teeth of the lower segment and/or teeth of the upper segment to fix the lower segment and the upper segment relative to the fixed segment.

In aspects, unlocking the adjustable spinal implant includes rotating a locking screw disposed along a longitudinal axis of the spinal implant in a first direction to proximally translate the locking segment. Locking the adjustable spinal implant may include rotating the locking 60 screw in a second direction opposite the first direction to distally translate the locking segment.

In some aspects, positioning the adjustable spinal implant includes approaching the intervertebral space from an anterior side of a patient's anatomy. Alternatively, positioning 65 the adjustable spinal implant includes approaching the intervertebral space from a posterior side of a patient's

4

anatomy. It is also contemplated that positioning the adjustable spinal implant includes approaching the intervertebral space from a lateral side of a patient's anatomy.

Further, to the extent consistent, any of the aspects described herein may be used in conjunction with any or all of the other aspects described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Various aspects of the present disclosure are described herein below with reference to the drawings, which are incorporated in and constitute a part of this specification, wherein:

FIG. 1 is a perspective view of an exemplary adjustable spinal implant provided in accordance with the present disclosure;

FIG. 2 is an exploded view of the adjustable spinal implant of FIG. 1, with parts separated;

FIG. 3 is a top view of the adjustable spinal implant of FIG. 1:

FIG. 4 is a rear view of the adjustable spinal implant of FIG. 1;

FIG. 5 is a side view of the adjustable spinal implant of FIG. 1 in an unlocked and compressed configuration;

FIG. 6 is a side view of the adjustable spinal implant of FIG. 1 in a locked and compressed configuration;

FIG. 7 is a side view of the adjustable spinal implant of FIG. 1 in an unlocked and expanded configuration;

FIG. 8 is a side view of the adjustable spinal implant of FIG. 1 in a locked and expanded configuration;

FIG. 9 is a perspective view of another locking segment provided in accordance with the present disclosure;

FIG. 10 is a perspective view of another lower segment provided in accordance with the present disclosure; and

FIG. 11 is a perspective view of another upper segment provided in accordance with the present disclosure.

DETAILED DESCRIPTION

Embodiments of the present disclosure are now described in detail with reference to the drawings in which like reference numerals designate identical or corresponding elements in each of the several views. As commonly known, the term "clinician" refers to a doctor, a nurse or any other care provider and may include support personnel. Additionally, the term "proximal" refers to the portion of the device or component thereof that is closer to the clinician and the term "distal" refers to the portion of the device or component thereof that is farther from the clinician. In addition, the term "cephalad" is known to indicate a direction toward a patient's head, whereas the term "caudal" indicates a direction toward the patient's feet. Further still, the term "lateral" is understood to indicate a direction toward a side of the body of the patient, i.e., away from the middle of the body of the patient. The term "posterior" indicates a direction toward the patient's back, and the term "anterior" indicates a direction toward the patient's front. Additionally, terms such as front, rear, upper, lower, top, bottom, and similar directional terms are used simply for convenience of description and are not intended to limit the disclosure. In the following description, well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail.

This disclosure relates generally to an adjustable spinal implant that is positionable within an intervertebral space in the anatomy of a patient in a compressed configuration and expandable within the intervertebral space to an expanded

configuration. The adjustable spinal implant includes a lower segment and an upper segment that are each pivotally coupled to a fixed segment and a locking segment that is translatable between a locked position and an unlocked position to fix the lower and upper segments in the compressed configuration or one of a plurality of expanded configurations.

Referring to FIGS. 1-5, an exemplary embodiment of an adjustable spinal implant 10 in accordance with the present disclosure includes a fixed segment 20, a locking segment 10 40, a lower segment 60, an upper segment 80, and a locking mechanism 90. The spinal implant 10 includes a row of teeth 11 (FIG. 5) in a stadium configuration or concentric ovals on a bottom surface 12. The bottom surface 12 is defined by a lower surface 21a of the fixed segment 20 and a lower 15 surface 61 of the lower segment 60. The spinal implant 10 includes a row of teeth 13 in a stadium configuration on a top surface 14 of the spinal implant 10. The top surface 14 is defined by an upper surface 21b of the fixed segment 20 and an upper surface 81 of the upper segment 80.

The fixed segment 20 slidably supports the locking segment 40 and pivotally supports the lower and upper segments 60, 80. When viewed from above or below, the fixed segment 20 is substantially U-shaped with an open end of the U-shape facing distally. The fixed segment 20 defines a 25 channel 22 that passes through the fixed segment 20 to define a longitudinal axis A-A of the spinal implant 10. The channel 22 includes a central section 24 and winged sections 26 extending laterally from the central section 24. The channel 22 is shaped to slidably receive the locking segment 30 40 as detailed below. The fixed segment 20 has distally extending end portions 32 on either side of the channel 22. Each end 32 defines a lateral opening 34 and reliefs 36. The lateral openings **34** define a pivot axis P-P that is orthogonal to the longitudinal axis A-A of the spinal implant 10. Each 35 lateral opening 34 is sized to receive a pivot pin 38 which may be frictionally secured within a respective one of the lateral openings 34. The reliefs 36 are defined between the ends 32 and the lower and upper surfaces 21a, 21b of the fixed segment 20.

The locking segment 40 is translatable along the longitudinal axis A-A of the spinal implant 10 to fix the lower and upper segments 60, 80 relative to the fixed segment 20. The locking segment 40 has a body 42 which is substantially rectangular in shape when viewed from above or below. The 45 body 42 defines a first or proximal opening 44 that passes vertically through the body 42 and a second or distal opening 46 that passes vertically through the body 42. The proximal and distal openings 44, 46 are separated by a central wall 45 of the body 42. The body 42 also defines a passage 52 that 50 extends along the longitudinal axis A-A of the spinal implant 10 and passes through a proximal wall 54 of the body 42 and the central wall 45 of the body 42. The body 42 also includes wings 48 that laterally extend from the body 42 adjacent the proximal wall 54. Each wing 48 includes a horizontal 55 section 49a and a vertical section 49b disposed at the end of the horizontal section 49a. The wings 48 are slidably received within the winged sections 26 of fixed segment 20 of the spinal implant 10. The distal end of the body 42 defines horizontal locking teeth **56** that are orthogonal to the longitudinal axis A-A of the spinal implant 10.

The lower segment 60 is pivotally coupled to the fixed segment 20 by proximally extending ends 62 disposed about the pivot axis P-P. Each end 62 includes a ring 64 that is positioned inside of the ends 32 of the fixed segment 20 and 65 about the pivot axis P-P to receive one of the pivot pins 38 and includes a depression 66 (FIG. 5) that proximally

6

extends from the respective ring 64. The depression 66 is received within a respective relief 36 of the fixed segment 20. The depression 66 supports a portion of the bottom teeth 11 (FIG. 5) that extend on the respective end 62 of the lower segment 60 such that the bottom teeth 11 transition smoothly between the respective end 62 and the respective end 32 of the fixed segment 20. The lower segment 60 also includes tines 70 that extend upwardly from a distal end portion of the lower segment 60 and define a gap 72 therebetween. The longitudinal axis A-A of the spinal implant 10 passes through the gap 72. Each of the tines 70 includes proximally facing horizontal teeth 74 that oppose the locking teeth 56 of the locking segment 40.

The upper segment 80 is pivotally coupled to the fixed segment 20 by proximally extending ends 82 disposed about the pivot axis P-P. Each end 82 includes a ring 84 that is positioned inside of the ends 32 of the fixed segment 20 and about the pivot axis P-P to receive one of the pivot pins 38. As shown, the rings 84 are positioned outside of the rings 64 of the lower segment **60**; however, it is contemplated that the rings 84 may be positioned inside of the rings 64. Each end 82 also includes a depression 86 that proximally extends from the respective ring **84** and is received within a respective relief 36 of the fixed segment 20. The depression 86 supports a portion of the upper teeth 13 that extend on the respective end 82 of the upper segment 80 such that the upper teeth 13 transition smoothly between the respective end 82 and the respective end 32 of the fixed segment 20. The upper segment **80** also includes a tongue **88** that extends downward from a distal end portion of the upper segment **80**. The tongue **88** is moveably disposed within the gap **72** defined between tines 70 of the lower segment 60. The tongue 88 defines proximally facing horizontal teeth 89 (FIG. 8) that oppose the locking teeth 56 of the locking segment 40.

The locking mechanism 90 translates the locking segment 40 to selectively fix the lower and upper segments 60, 80 relative to one another. The locking mechanism 90 includes a threaded insert 92, a locking screw 94, and a bushing 98.

The threaded segment 92 is disposed within the proximal opening 44 of the locking segment 40. The locking screw 94 includes a head 95, a threaded shank 96 extending from the head 95, and a distal end portion 97 extending from the threaded shank 96. The bushing 98 is disposed within the distal opening 46 of the locking segment 40 and is secured about the distal end portion 97 of the locking screw 94.

With reference to FIGS. 5 and 6, the locking segment 40 has an unlocked position (FIG. 5) and a locked position (FIG. 6). In the unlocked position, the locking teeth 56 of the locking segment 40 are spaced apart from the teeth 74, 89 of the lower and upper segments 60, 80, respectively, such that the upper and lower segments 60, 80 are pivotable relative to the fixed segment 20 and one another. In the locked position, the locking teeth 56 of the locking segment 40 are engaged with the teeth 74, 89 of the lower and upper segments, 60, 80, respectively, such that the upper and lower segments 60, 80 are fixed relative to the fixed segment 20 and one another. It will be appreciated that the locking teeth 56 of the locking segment 40 are dimensioned to engage teeth 74 of each tine 70 of the lower segment 60 and teeth 89 of the tongue 88 of the upper segment simultaneously.

The locking mechanism 90 translates the locking segment 40 between the unlocked and locked positions. The head 95 of the locking screw 94 is fixed within the central section 24 of the channel 22 of the fixed segment 20. The head 95 may include a flange 95a that is received within a recess 24a defined in the central section 24 to prevent longitudinal

movement of the locking screw 94 relative to the fixed segment 20. The threaded shank 96 (FIG. 3) extends along the longitudinal axis A-A of the spinal implant 10 within the channel 22 of the fixed segment 20 and through the passage 52 of the locking segment 40. As the threaded shank 96 passes through the proximal opening 44 of the locking segment 40, the threaded shank 96 passes through and threadably engages the threaded insert 92. The threaded shank 96 extends through the central wall 45 between the proximal and distal openings 44, 46 of the locking segment 40 and the bushing 98 is secured about the distal end portion 97 of the locking screw 94 to prevent the distal end portion 97 from withdrawing through the central wall 45. The bushing 98 may engage the central wall 45 to limit distal translation of the locking segment.

Referring to FIGS. 5 and 7, the spinal implant 10 has a parallel or collapsed configuration (FIG. 5) and a fully expanded configuration (FIG. 7). In the collapsed configuration, the lower segment 60 and the upper segment 80 are approximated relative to one another such that lower surface 20 61 of the lower segment 60 and the upper surface 81 of the upper segment 80 are substantially parallel to one another. In addition, in the collapsed configuration, the lower surface 61 of the lower segment 60 is aligned with lower surface 21a of the fixed segment 20 such that the bottom surface 12 of 25 the spinal implant 10 is substantially planar and the upper surface 81 of the upper segment 80 is aligned with the upper surface 21b of the fixed segment 20 such that the top surface 14 of the spinal implant 10 is substantially planar. In the collapsed configuration, the tines 70 of the lower segment 60 30 may abut the upper segment 80 and/or the tongue 88 of the upper segment 80 may abut the lower segment 60 to limit the pivoting of the lower and upper segments 60, 80 relative to the fixed segment 20. With particular reference to FIG. 6, in the collapsed configuration the lower and upper segments 35 60, 80 form a beveled distal or leading end 18 (FIG. 6) of the spinal implant 10.

In one of a plurality of expanded configurations (i.e., any configuration between the fully compressed configuration and the fully expanded configuration), the lower and upper 40 segments 60, 80 are pivoted apart from one another about the pivot axis P-P such that the lower surface 61 of the lower segment 60 and the upper surface 81 of the upper segment **80** are askew relative to one another. As shown in FIG. 7, the lower surface 61 of the lower segment 60 defines an angle 45 θ_1 with the lower surface 21a of the fixed segment 20 and the upper surface 81 of the upper segment 80 defines an angle θ_2 between upper surface 21b of the fixed segment 20. In the expanded configurations at least one of the angles θ_1 and θ_2 is in a range between about 150° and about 175° such that 50° a height of the spinal implant 10 between the lower surface 61 of the lower segment 60 and the upper surface 81 of the upper segment 80 adjacent the tines 70 and the tongue 88 is greater than the height of the fixed segment 20 between the lower and upper surfaces 21a, 21b thereof. It is contem- 55 plated that in the expanded configurations each of the angles θ_1 and θ_2 may be in a range of about 150° to about 180° (e.g., about 165°). The interaction of the depressions 66, 86 of the lower and upper segments 60, 80, respectively, and the reliefs 36 of the fixed segment 20 may form stops to limit the 60 range of angles θ_1 and θ_2 .

It will be appreciated that manufacturing the spinal implant 10 by standard metal machining methods (e.g., using a lathe, mill, EDM, etc.) may be difficult. Instead, it is contemplated that the spinal implant 10 are manufactured 65 using additive manufacturing methods. One such additive manufacturing method commonly referred to as Selective

8

Laser Powder Processing (SLPP) utilizes powdered metal and a laser which sinters or cures the metal in a selective fashion according to the design intent in thin layers, e.g., layers may have a thickness of about 250 µm. The object (e.g., spinal implant 10) is built layer by layer to allow for more design options and features which would be difficult to be machined. In addition, as spinal implant 10 is individually manufactured, it is possible to customize the spinal implant 10 for a designated patient. Suitable manufacturing methods are disclosed in U.S. Pat. No. 8,590,157, the entire contents of which are hereby incorporated by reference herein.

The spinal implant 10 may be constructed from titanium, a titanium-alloy, a cobalt-chromium alloy, a ceramic, or any other suitable biocompatible material. It is also contemplated that the spinal implant 10 may be three-dimensionally printed from a biocompatible polymer.

Referring to FIGS. 5-8, a method of inserting the adjustable spinal implant 10 into a desired intervertebral space is disclosed in accordance with the present disclosure. Initially referring to FIG. 6, the spinal implant 10 is in the collapsed configuration with the locking segment 40 in the locked position. In such a configuration, the spinal implant 10 has a minimum height to aid in insertion of the spinal implant 10 into the desired intervertebral space with each of the angles θ_1 and θ_2 about 180°. As shown in FIG. 6, in the collapsed configuration, the lower segment 60 and the upper segment **80** cooperate to form the beveled leading end **18** of the spinal implant 10 which may further assist in insertion of the spinal implant 10 into the desired intervertebral space. As detailed above, the locking segment 40 is in the locked position, to prevent the lower and upper segments 60, 80 from pivoting relative to the fixed segment 20. An insertion tool (not shown) may engage the channel 22 of the fixed segment 20 of the spinal implant 10 to insert the spinal implant 10 into the desired intervertebral space. It is contemplated that an anterior approach or a posterior approach may be used to insert the spinal implant 10 in accordance with the disclosed method. Alternatively, it is contemplated that a lateral approach may be used to insert the spinal implant in accordance with the disclosed method.

When the spinal implant 10 is positioned in a desired intervertebral space, a rotatable instrument (not shown) is inserted into the channel 22 to engage the head 95 of the locking screw 94. The rotatable instrument may be a screwdriver or similar instrument and may be integrally formed with the insertion tool such that the rotatable instrument is engaged with the head 95 of the locking screw 94 during insertion of the spinal implant into the desired intervertebral space. Alternatively, the rotatable instrument may be a separate instrument such that the insertion instrument is removed before the rotatable instrument engages the head 95 of the locking screw **94**. Further, it is contemplated that the rotatable instrument may be inserted through the insertion instrument such that the insertion tool may remain engaged with the channel 22 of the fixed segment 20 when the rotatable instrument engages the head 95 of the locking screw 94.

With the rotatable instrument engaged with the head 95 of the locking screw, the rotatable instrument is rotated to effect rotation of the locking screw 94 in a first direction such that the threaded insert 92 is proximally translated along the threaded shank 96 of the locking screw 94. As the threaded insert 92 is proximally translated along the threaded shank 96, the threaded insert 92 engages the proximal wall 54 of the locking segment 40 that defines the proximal opening 44 of the locking segment 40 to proximally translate the locking

segment 40 towards the unlocked position as shown in FIG. 5. As the locking segment 40 translates proximally, the locking teeth 56 of the locking segment 40 are disengaged from the teeth 74 of the lower segment 60 and the teeth 89 of the upper segment 80.

When the spinal implant 10 is positioned in the desired intervertebral space with the locking segment 40 in the unlocked position, at least one of the lower and upper segments 60, 80 is pivoted relative to the fixed segment 20 about the pivot axis P-P towards an expanded configuration as shown in FIG. 7. An expansion instrument may be used to pivot the lower and upper segments 60, 80 about the pivot axis P-P. As the lower and upper segments 60, 80 are pivoted about the pivot axis P-P, the spinal implant 10 is transitioned 15 locking teeth 56 detailed above. The increased engagement towards the expanded configuration until the leading end 18 of the spinal implant 10 has a desired height. Upon expansion each of the angles θ_1 and θ_2 may bin in a range of about 150° to about 180°. More preferably, in the expanded configuration each of the angles θ_1 and θ_2 are between about θ_2 160° and about 170°. Most preferably, in the expanded configuration each of the angles θ_1 and θ_2 are about 165°. When the distal end portion 18 of the spinal implant 10 reaches a desired height, the rotatable instrument inserted in the channel 22 is rotated to effect rotation of the locking 25 screw 94 in a second direction opposite the first direction to distally translate the threaded insert distally along the threaded shank **96** of the locking screw **94**. As the threaded insert 92 is translated distally along the threaded shank 96, the threaded insert 92 engages the central wall 45 of the 30 locking segment 40 to translate the locking segment 40 distally towards the locked position until the locking teeth 56 of the locking segment 40 are engaged with the teeth 74 of the lower segment 60 and the teeth 89 of the upper segment 80 to fix the lower segment 60 and the upper 35 segment 80 in the expanded configuration as shown in FIG. **8**. As the threaded insert **92** engages the central wall **45** of the locking segment 40, the bushing 98 may engage the central wall 45 to retain the locking screw 94 within the locking segment 40. With the spinal implant 10 in the 40 expanded configuration and the locking segment 40 in the locked position, the rotatable instrument is then withdrawn from the channel 22 to disengage from the head 95 of the locking screw 94.

Referring now to FIGS. 9-11, an alternative locking 45 segment 140, lower segment 160, and upper segment 180 are provided in accordance with the present disclosure. The locking segment 140, the lower segment 160, and the upper segment 180 are similar to the locking segment 40, lower segment 60, and upper segment 80, respectively, with like 50 features represented with a similar label with a "1" prefix. For reasons of brevity, only the differences with respect to the locking segment 140, the lower segment 160, and the upper segment 180 will be detailed below.

With particular reference to FIG. 9, the locking segment 55 140 includes arcuate horizontal locking teeth 156 in a plane substantially parallel to the longitudinal axis A-A of the spinal implant 10. As shown, the arcuate horizontal locking teeth 156 have a semi-circular profile of about 180 degrees in a plane substantially parallel to the longitudinal axis A-A, 60 e.g., when viewed from above. It is contemplated that the arcuate horizontal locking teeth 156 may form a circular profile in a range of about 75 degrees to about 215 degrees.

With particular reference to FIG. 10, the lower segment 160 includes tines 170 that extend upwardly from a distal 65 end portion of the lower segment 160 and define a gap 172 therebetween. Each of the tines 170 includes proximally

10

facing arcuate horizontal teeth 174 that oppose the arcuate locking teeth 156 of the locking segment 140.

With reference to FIG. 11, the upper segment 180 includes a tongue 188 that extends downward form a distal end 5 portion of the upper segment 180. The tongue 188 is moveably disposed within the gap 172 that is defined between the tines 170 of the lower segment 160. The tongue 188 defines proximally facing arcuate horizontal teeth 189 that oppose the locking teeth 156 of the locking segment 10 **140**.

The engagement of the arcuate locking teeth **156** and the arcuate horizontal teeth 174 of the lower segment 160 and the arcuate horizontal teeth **189** of the upper segment may provide increased engagement area as compared to the area may allow the spinal implant 10 to withstand additional loading which may be seen in lower portions of the spine (e.g., the lumbar or sacrum regions).

While several embodiments of the disclosure have been shown in the drawings, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Any combination of the above embodiments is also envisioned and is within the scope of the appended claims. Therefore, the above description should not be construed as limiting, but merely as exemplifications of particular embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

What is claimed:

- 1. An adjustable spinal implant comprising:
- a fixed segment defining a channel disposed about a longitudinal axis of the spinal implant;
- a locking segment translatable within the channel of the fixed segment along the longitudinal axis between a locked position and an unlocked position, the locking segment defining a proximal opening passing vertically therethrough, the locking segment having a distal end portion including locking teeth;
- a lower segment pivotally coupled to the fixed segment about a pivot axis that is transverse to the longitudinal axis, the lower segment having a distal end portion including teeth that oppose the locking teeth;
- an upper segment pivotally coupled to the fixed segment about the pivot axis, the upper segment having a distal end portion including teeth that oppose the locking teeth, the adjustable spinal implant having a collapsed configuration wherein the distal end portions of the lower and upper segments define a first height and an expanded configuration wherein the distal end portions of the lower and upper segments define a second height greater than the first height; and
- a locking mechanism engageable with the locking segment to translate the locking segment longitudinally between locked and unlocked positions to fix the lower and upper segments relative to the fixed segment; and
- wherein, in the unlocked position, the locking teeth are longitudinally spaced apart from the teeth of the lower and upper segments.
- 2. The adjustable spinal implant according to claim 1, wherein the locking teeth of the locking segment are engaged with the teeth of the lower and upper segments to fix the lower and upper segments relative to the fixed segment to define the locked position.
- 3. The adjustable spinal implant according to claim 1, wherein a bottom surface of the spinal implant is defined by a lower surface of the lower segment and a lower surface of

the fixed segment, and wherein in the collapsed configuration the lower surfaces of the lower segment and the fixed surface are disposed within the same linear plane and in the expanded configuration the lower surface of the lower segment and the lower surface of the fixed segment define a 5 non-zero first angle therebetween.

- 4. The adjustable spinal implant according to claim 3, wherein the first angle is in a range of 135° to 179°.
- 5. The adjustable spinal implant according to claim 1, wherein a top surface of the spinal implant is defined by an 10 upper surface of the upper segment and an upper surface of the fixed segment, and wherein in the collapsed configuration the upper surfaces of the upper segment and the fixed surface are disposed within the same linear plane and in the expanded configuration the upper surface of the upper 15 segment and the upper surface of the fixed segment define a non-zero second angle therebetween.
- 6. The adjustable spinal implant according to claim 5, wherein the second angle is in a range of 135° to 179°.
- 7. The adjustable spinal implant according to claim 1, 20 wherein the distal end portion of the lower segment includes tines that define a gap therebetween, each tine including the teeth that oppose the locking teeth.
- 8. The adjustable implant according to claim 7, wherein the distal end portion of the upper segment includes a tongue 25 positionable within the gap defined between the tines of the lower segment, the tongue including the teeth that oppose the locking teeth.
- 9. The adjustable spinal implant according to claim 1, wherein the locking mechanism includes a locking screw 30 disposed within the channel of the fixed segment and the passage of the locking segment.
- 10. The adjustable implant according to claim 9, wherein the locking mechanism includes a threaded insert disposed on a threaded shank of the locking screw to engage walls 35 defining the proximal opening of the locking segment to transition the locking segment between the locked and unlocked positions.
- 11. The adjustable spinal implant according to claim 1, wherein the locking teeth are arcuate in a plane parallel to 40 the longitudinal axis.
- 12. The adjustable implant according to claim 11, wherein the locking teeth have a semi-circular profile in the plane parallel to the longitudinal axis.
- 13. A method of inserting an adjustable spinal implant, the 45 method comprising:
 - positioning an adjustable spinal implant into an intervertebral space in a collapsed configuration, a distal end portion of the adjustable spinal implant having a first height in the collapsed configuration;

unlocking the adjustable spinal implant when the adjustable spinal implant is positioned within the interverte-

12

bral space by disengaging locking teeth of a locking segment from teeth of a lower segment and teeth of an upper segment such that the locking teeth are longitudinally spaced apart from the teeth of the lower and upper segments;

transitioning the adjustable spinal implant to an expanded configuration by pivoting at least one of the lower segment or the upper segment of the adjustable spinal implant about a pivot axis defined by a fixed segment of the adjustable spinal implant such that a distal end portion of the adjustable spinal implant has a second height greater than the first height; and

locking the adjustable spinal implant in the expanded configuration by engaging the locking teeth of the locking segment with the teeth of the lower segment and the teeth of the upper segment to fix the lower segment and the upper segment relative to the fixed segment.

- 14. The method according to claim 13, wherein unlocking the adjustable spinal implant includes rotating a locking screw disposed along a longitudinal axis of the spinal implant in a first direction to proximally translate the locking segment, and wherein locking the adjustable spinal implant includes rotating the locking screw in a second direction opposite the first direction to distally translate the locking segment.
- 15. The method according to claim 14, wherein positioning the adjustable spinal implant includes approaching the intervertebral space from an anterior side of a patient's anatomy.
- 16. The method according to claim 14, wherein positioning the adjustable spinal implant includes approaching the intervertebral space from a posterior side of a patient's anatomy.
- 17. The method according to claim 13, wherein positioning the adjustable spinal implant includes approaching the intervertebral space from an anterior side of a patient's anatomy.
- 18. The method according to claim 13, wherein positioning the adjustable spinal implant includes approaching the intervertebral space from a posterior side of a patient's anatomy.
- 19. The adjustable spinal implant according to claim 1, wherein any one of the locking teeth of the locking segment simultaneously engages at least one of the teeth of each of the lower and upper segments.
- 20. The adjustable spinal implant according to claim 1, wherein the lower and upper segments are pivotally coupled to the fixed segment by a pivot pin.

* * * *